

HCV LOOKBACK GUIDANCE

Committee Update

**Paul Mied, Ph.D., Deputy Director
Division of Emerging & Transfusion Transmitted Diseases, OBRR, CBER, FDA**

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Current FDA Thinking on Revisions to the June 1999 HCV Lookback Guidance Document

“Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).”

FDA published its most recent guidance on HCV lookback as a draft document for comment on June 22, 1999. This document contained proposed recommendations for extension of HCV lookback to address donor testing since May 1990, using EIA 1.0, as recommended by the PHS Advisory Committee on Blood Safety and Availability at its January 1999 meeting. The comment period for this guidance closed on August 23, 1999. Comments were summarized and discussed at the August 1999 meeting of the PHS Advisory Committee, the September 1999 meeting of the Blood Products Advisory Committee, and the November 1999 Annual Meeting of the American Association of Blood Banks.

Status of the HCV Lookback Guidance Implementation

According to CDC's nationwide evaluation of the effectiveness of targeted notification for HCV infection, as of December 1999 approximately 80% of blood collection establishments have completed at least 90% of their consignee notifications based on EIA 2.0 and EIA 3.0 multiantigen testing. As stated in the June 1999 FDA guidance document, the deadline for completion of this notification of consignees is March 23, 2000. Approximately 20% of blood establishments (mostly the smaller ones) have begun and 15% have completed notification of consignees based on EIA 1.0 single antigen screening. Transfusion services have completed the notification process for 80% of recipients of components from EIA 2.0 and EIA 3.0 multiantigen tested donors. According to survey respondents, the notification process had been completed for 33,098 recipients, of whom 70% are deceased, 23% were actually notified, 12% were tested, 2% were positive, and half of those recipients learned for the first time that they were positive. Thus, the effectiveness of the targeted lookback for identifying HCV positive recipients is approximately 1%. If we were to project this yield to a nationwide level, it is estimated that as of December 1999, approximately 900 recipients have learned for the first time that they are HCV positive as a result of the targeted HCV lookback effort.

FDA's Current Thinking Regarding Revisions to the June 1999 Guidance

1. The scope of the indefinite search of records (prior to January 1, 1988) should be limited to computerized electronic records. This would make the pre-1990 lookback based on “readily retrievable records” as FDA stated in the June 1999 guidance meaningful, but would limit it in a practical way. All other record searches such as microfiche and paper records would extend back to January 1, 1988 for a current

repeatedly reactive donation or for a repeatedly reactive donation found in the retrospective search of records.

2. Nucleic Acid Testing (or NAT) as a trigger for lookback both prospectively and retrospectively should be included. Use of NAT as an additional test to clarify other screening test results would be permitted, subject to certain limitations. For example, a positive NAT can confirm a repeatedly reactive result and trigger lookback, but considering that in some cases of HCV infection the viremia is intermittent or is resolved, a negative NAT cannot obviate lookback for a repeatedly reactive donation, and a supplemental test for antibody would still need to be performed as a basis for determining the actions to be taken with regard to lookback.
3. Consideration of supplemental test results of record for the RIBA 1.0 and the Abbott Neutralization-peptide assay as possible indicators for recipient notification in lookback based on EIA 1.0 should be added.

FDA plans to issue a draft revised FDA Guidance for Industry document on HCV Lookback for implementation in the near future.

Timeframe for Implementation of HCV Lookback

This table summarizes the timeframes for beginning and completing consignee notification that would be included in the revised FDA Guidance for Industry document.

Consignee Notification by Blood Establishments

	<u>Begin by:</u>	<u>Complete by:</u>
EIA 2.0 and 3.0: For prior collections dating back to <u>1/1/88</u>	(March 23, 1999)	March 23, 2000
EIA 2.0 and 3.0: For prior collections extending back <u>indefinitely</u> (computerized records)	As soon as feasible	12 months after date of publication of revised guidance for implementation
EIA 1.0: For prior collections extending back to <u>1/1/88</u> <u>or indefinitely</u> (computerized records)	6 months after date of publication of revised guidance for implementation	15 months after date of publication of revised guidance for implementation

The next table summarizes the timeframes for beginning and completing recipient notification that would be included in the revised FDA Guidance for Industry document.

Recipient Notification by Transfusion Services

	<u>Begin by:</u>	<u>Complete by:</u>
Prospective notifications	Upon receipt of notification	Within 12 weeks following receipt of notification
Retrospective notifications	Upon receipt of notification	Within 1 year following receipt of notification (For <u>all</u> notifications: 27 months after date of publication of revised guidance for implementation)